

CLAIMS

ASSAY FOR ANTI TRANSGLUTAMINASE ANTIBODIES DETECTION USEFUL IN CELIAC DISEASE DIAGNOSIS

1. An assay to detect IgA or IgG anti-transglutaminase antibodies in liquid samples which comprises:

- Immunocomplex formation between antibodies in the samples and the antigen tissue transglutaminase, obtained from natural sources or by recombinant DNA technology. The antigen is conjugated to a colored substance and deposited onto an inert support which allows the release of the conjugated when it comes into contact with a liquid sample.
- Reaction of the immunocomplexes described in a) with the same antigen tissue transglutaminase adsorbed onto a reactive zone of a membrane promoting its deposition on this zone. *no correlation step: compor sand?*

2. *An assay* [to detect IgA or IgG anti-transglutaminase antibodies] according to claim 1, wherein the adsorbed antigen is fixed onto a nitrocellulose or nylon membrane with 5 to 10 μ m pore size that allows a lateral flow of reactants.

3. *An assay* [to detect IgA or IgG anti-transglutaminase antibodies] according to claim 1, wherein the colored substance conjugated to the antigen is colloidal gold or colored latex particles.

4. *An assay* [to detect IgA or IgG anti-transglutaminase antibodies] according to claim 1, wherein the excess of the conjugated antigen reacts with a reagent adsorbed onto another zone of the same membrane resulting in a second colored signal that can be used to check the performance of the assay.

5. Procedure according to claim 1 wherein the assay detects IgA or IgG anti-transglutaminase antibodies in samples of human serum, plasma, or blood in just one-step.